

**New Jersey Department of Health
Clinical Laboratory Improvement Services**

www.nj.gov/health/phel/clis.shtml

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**GENERAL INSTRUCTIONS FOR COMPLETING AN
APPLICATION FOR LICENSURE OF A CLINICAL LABORATORY
(UNDER THE PROVISIONS OF N.J.S.A. 45:9-42.26 ET SEQ.)**

NOTICE TO ALL APPLICANTS FOR A CLINICAL LABORATORY LICENSE:

Under the provisions of N.J.S.A. 45:9-42.26 et seq. and N.J.A.C. 8:44-2.1 et seq., the signed Application for a Clinical Laboratory License, and all requested attachments, must be completed in full and returned to the above address with the appropriate fee. Fees are non-refundable and incomplete applications will not be processed.

Checks or money orders should be made payable to the “*New Jersey Department of Health*” (NJDOH) and include the CLIS ID Number for all renewals. You may also make your payment using the electronic payment link on the Clinical Laboratory Improvement Services website (<http://nj.gov/health/phel/clis.shtml>). Please include a photocopy of your check, money order or electronic payment receipt.

The NJDOH must be notified by certified mail within fourteen days of the following laboratory changes:

- **Name**
- **Address (Must include \$100 fee)**
- **Ownership**
- **Director**
- **Hours**
- **Termination of Tests**

A license issued under N.J.S.A. 45:9-42.26 et seq. and N.J.A.C. 8:44-2.1 et seq. **IS NOT TRANSFERABLE.** A new application must be submitted if there is a change in ownership.

INITIAL LICENSURE PROCESS [Check appropriate box on top of page one of application (CL-3)]:

1. Submit completed license application (CL-3) and materials below to CLIS with the appropriate fees.
2. Submit ownership form (CL-9).
3. Ensure that Laboratory Director is licensed by the Board of Medical Examiners as a Bioanalytical Laboratory Director and submit proof of license, if required. Refer to our statute and rules.
4. Submit completed Personnel Qualification forms (CL-34) for the following:
 - Laboratory Director
 - Technical Supervisor(s)
 - General Supervisor(s)
 - Testing personnel

Evaluate that personnel meet state personnel requirements. If the laboratory director is not a clinical pathologist, you are required to have a technical supervisor who meets the requirements of N.J.A.C. 8:44-2.5(c) for all requested specialties.

5. Have a general supervisor who meets the requirements of N.J.A.C. 8:44-2.4(c) for all requested specialties and is on the laboratory premises during all hours in which tests are routinely performed
6. Submit plan of the premises or photograph of the area to be occupied for the operation of the laboratory.
7. Demonstrate test performance accuracy by submitting either documentation of successful participation in an approved proficiency testing survey or, when an acceptable proficiency testing survey is unavailable, provide acceptable validation documentation for each test and/or examination offered to clients.
8. For laboratories located outside of New Jersey, which are seeking licensure because they operate collection stations in New Jersey, submit a copy of an on-site survey report performed by a regulatory or accrediting agency.

The license shall be conspicuously displayed by the licensee on the laboratory premises.

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

ANNUAL RENEWAL OF LICENSURE (Check appropriate box on top of page one):

All clinical laboratory licenses shall be issued on or before January 1 of each calendar year and shall expire on December 31 of each calendar year.

The NJDOH will provide instructions on our website for licensure renewal on or before October 1 of each year to be properly completed and returned to the Department, together with the appropriate licensure renewal fee, **no later than November 1**.

SPECIFIC INSTRUCTIONS FOR COMPLETING THE CL-3 APPLICATION FOR LICENSURE OF A CLINICAL LABORATORY

When completing your license application, please pay particular attention to the following:

Page 1:

Fill in the requested information in all fields and attach a completed CL-9 form, a list of current laboratory equipment, and a list of laboratory personnel.

Pages 3-5:

(14) Laboratory Tests Performed- Instructions found on page 3. Laboratory workload data (pages 3-5): The annual numbers of tests or specimens must be entered. Refer to "Guidelines for Counting Tests for CLIS-Laboratory Workload Data" below.

For a listing of FDA-approved analyte specialties, refer to <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>.

Enrollment in proficiency testing – Please indicate on page 5, your proficiency testing provider(s), e.g., CAP, AAB, API, etc.

For a listing of CMS-Approved Proficiency Testing Programs, refer to: <http://www.cms.gov/CLIA/downloads/ptlist.pdf>

Pages 7 and 8:

(19) + (20)

Laboratories performing only CLIA-waived tests can skip to Page 8. Laboratories performing any CLIA non-waived tests must complete page 7. You do not need to check off and pay for the additional specialty of CLIA-waived tests if those tests you perform fall under another specialty for which you are also applying. For example, if you perform moderate or high complexity Virology testing, you do not need to pay a separate CLIA-waived fee for your Rapid Flu testing.

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

GUIDELINES FOR COUNTING TESTS FOR CLIS LABORATORY WORKLOAD DATA

- For **histocompatibility**, each HLA typing (including disease associated antigens), HLA cross match is counted as one test.
- For **microbiology**, susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per specimen regardless of the extent of identification, number of organisms isolated and number of test/procedures required for identification.
- Testing for allergens should be counted as one test per individual allergen.
- For **chemistry** profiles, each individual analyte is counted separately.
- For **urinalysis**, microscopic and macroscopic examinations, each count as one test. Macroscopics (dipsticks) are counted as one test regardless of the number of reagent pads on the strip.
- For **complete blood counts**, each measured individual analyte that is ordered and reported is counted separately. Differentials are counted as one test.
- Do not count calculations (e.g., A/G ratio, eGFR, MCH, and T7), quality control, quality assurance and proficiency testing assays.
- For **immunohematology**, each ABO, Rh, antibody screen, cross match or antibody identification is counted as one test.
- For **cytology**, each slide (not case) is counted as one test for both Pap smears and non-gynecologic cytology.
- For **cytogenetics**, the number of tests is determined by the number of specimen types processed on each patient, e.g., a bone marrow and a venous blood specimen received on one patient is counted as two tests.

Collection Stations and Out-of State Laboratories

For collection stations, complete a CL-18 form and indicate the actual address of the collection station, and the name and address of the parent laboratory. Each collection station has a unique CLIS ID. **N.J.S.A. 45:9-42.27.a** defines a collection station as “any facility used for the collection, processing and transmission of specimens to another facility for the performance of clinical tests.”

Out of State laboratories that have a collection station in the State of New Jersey or that have employees directly involved in the collection or transport of specimens from New Jersey facilities are required to obtain a clinical laboratory license.

Test Expansion/Addition

Licensure in a specialty does not allow you to add tests or subspecialties under that specialty without approval from CLIS. If your laboratory intends to offer an additional test or specialty, you must submit:

- A written request signed by the laboratory director.
- Documentation of successful participation in an approved proficiency testing program. If proficiency is unavailable, acceptable verification and validation documentation must be submitted.
- For new specialties an additional fee must be submitted. Please refer to CL-3, Page 7 for fee categories.

Mailing Address/Written Correspondence

Please enclose a return mailing label or envelope with all applications for accurate delivery of the license.

Regular Mail

Joan Mikita, Licensing Unit
PHEL/Clinical Laboratory Improvement Services
New Jersey Department of Health
P.O. Box 361
Trenton, NJ 08625-0361

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